STATE OF MISSOURI
MISSOURI BOARD OF PHARMACY

IN RE:	)	
	)	
WALGREENS #05278	)	Case No. 2017-002916 - V1
Permit No. 2000157695	)	
3845 Broadway	)	
Kansas City, MO 64111,	)	
	)	

SETTLEMENT AGREEMENT BETWEEN
THE MISSOURI BOARD OF PHARMACY AND WALGREEN CO.
D/B/A WALGREENS #05278

Come now Walgreens #05278 ("Respondent" or "Licensee") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's pharmacy permit will be subject to additional discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing before the Board, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded him by law, including the right to a hearing before the Board of the charges against it; the right to appear and be represented by counsel; the right to have all charges against it proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record concerning the charges pending against it; and the right to recover attorney's fees incurred in defending this action against its permit. Being aware of these rights provided by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to it.

Respondent acknowledges that it has received a copy of the Violation Complaint filed against it with the Board, the investigative report, and other documents relied upon by the Board in determining there was cause to impose additional discipline against Respondent's permit.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's pharmacy permit, numbered 2000157695, is subject to additional disciplinary action by the Board in accordance with the provisions of Chapters 324 and 338, RSMo.

JOINT STIPULATION OF FACTS

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.140, RSMo, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Respondent is licensed by the State of Missouri as a pharmacy, permit number 2000157695. Respondent's permit was at all times relevant herein current and active.

3. Respondent's permit to practice pharmacy was on probation through March 16, 2019.

4. At all times relevant hereto, Respondent has had three different Pharmacists-in-Charge ("PIC").

Prior Disciplinary Action

5. On or about February 16, 2016, Respondent signed a Settlement Agreement (the "2016 Agreement") with the Board which contained a Joint Stipulation of Facts, Joint Conclusions of Law and a Joint Agreed Disciplinary Order for failing to maintain adequate security of controlled substances resulting in significant losses of controlled substances.

6. The 2016 Agreement was executed by the Board on March 2, 2016. It went into full effect on March 17, 2016.

7. Pursuant to the 2016 Agreement, Respondent's license was placed on probation for three (3) years and imposed terms of discipline which were agreed to be followed during the term of probation.

8. The Disciplinary Order in the 2016 Agreement required that:

> B. Respondent shall comply with all applicable provisions of Chapter 338, Chapter 195, Chapter 196 and all applicable federal and state pharmacy/drug laws and regulations and all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

9. The Disciplinary Order in the 2016 Agreement also provides:

> I. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.

10. The Disciplinary Order in the 2016 Agreement further provides:

> 2. . . . that in the event the Board determines that Respondent has violated any term or condition of this Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke or otherwise lawfully discipline Respondent.

11. The Disciplinary Order in the 2016 Agreement finally provides:

> 4. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. . . .

Subsequent Violations

May 2017 Investigation

12. On or about January 6, 2017, the Board received a controlled substance audit/reconciliation from the Pharmacy for the timeframe of June 9, 2016 through December 9, 2016. It showed Schedule II through IV controlled substance losses of 11,717 dosage units and 3,290 mL. It also showed losses of 2,643 dosage units of products containing pseudoephedrine.

13. Controlled substance loss reports submitted by the Pharmacy to the Drug Enforcement Administration (DEA) and the Missouri Board of Narcotics and Dangerous Drugs (BNDD) on April 21, 2017, showed losses of 9,256 dosage units and 2,980 mL of various controlled substances. The reports did not show additional losses of 2,461 dosage units and 310 mL of various controlled substances and 643 dosage units of products containing pseudoephedrine.

14. The Pharmacy noted on the loss reports that "initial inventory on June 9, 2016 wasn't done correctly."

15. The PIC counted all of the controlled substances on hand at the store for the audit and then sent the counts to Walgreens RX Integrity.

16. All details of the report of audit submitted to the Board were determined by Walgreens RX Integrity. The PIC had no involvement in the report of audit other than conducting the count and making the report as instructed by RX Integrity.

17. On or about June 6, 2017, the Pharmacy submitted an amended report of loss to the BNDD to report all losses. The amended report also contained an adjustment to the loss amounts of Oxycodone 30mg immediate relief tablets from 30 to 275 and Phenobarbital 30mg and 60mg, the losses for which were entered "backwards."

18. The Pharmacy submitted another amended report of loss to the BNDD on June 6, 2017 to correct the loss amount for Morphine Sulfate ER 60 mg tablets.

19. On or about July 10, 2017, the Board received a controlled substance audit/reconciliation from the Pharmacy for the timeframe of December 9, 2016 through June 9, 2017. It showed Schedule II through IV controlled substance losses of 2,036 dosage units and 1,227 mL, and of 1,214 dosage units of products containing pseudoephedrine.

20. 20 CSR § 2220-2.010(1)(H) states:

> (H) Pharmacies must maintain adequate security in order to deter theft of drugs by personnel or the public. Sufficient alarm systems or locking mechanisms must be in place if the pharmacy is located in a facility into which the public has access and the pharmacy's hours of operation are different from those of the remainder of the facility.

21. Respondent failed to provide adequate security or effective controls and procedures to guard against and deter loss and/or theft of its controlled substances in violation of 20 CSR § 2220-2.010(1)(H).

September 26, 2017 Inspection

22. On or around September 26, 2017, Board Inspector Elaina Wolzak conducted a routine inspection of the Pharmacy.

23. She observed numerous violations of Missouri law.

24. A Compliance Notice was issued by Inspector Wolzak at the end of the inspection for certain violations.

25. A Response to the Compliance Notice was signed by the PIC and submitted to the Board.

a. Failure to Display Technician Registration Certificate

26. During her September 26, 2017, inspection of the Pharmacy, Inspector Wolzak observed two pharmacy technicians working who did not have a registration certificate on display at the Pharmacy.

27. K.P and L.B., who were pharmacy technicians at the Pharmacy, posted certificates that had expired on May 31, 2017.

28. Missouri law requires:

> 4. A certificate of registration issued by the board shall be conspicuously displayed in the pharmacy or place of business where the registrant is employed.
>
> 5. Every pharmacy technician who desires to continue to be registered as provided in this section shall, within thirty days before the registration expiration date, file an application for the renewal, accompanied by the fee prescribed by the board. The registration shall lapse and become null and void thirty days after the expiration date. § 338.013.4-.5, RSMo.

29. Missouri law also requires:

> (1)(B) A person may be employed as a technician once a completed application and the required fee is received by the board. The board will provide either a registration certificate that shall be conspicuously displayed . . . 20 CSR § 2220-2.700(1)(B).

30. By failing to display valid registration certificates for K.P and L.B., the Pharmacy was in violation of § 338.013.4-.5, RSMo, and 20 CSR § 2220-2.700(1)(B).

b. Failure to Maintain Pharmacy in Sanitary Condition

31. During her September 26, 2017, inspection of the Pharmacy, Inspector Wolzak found that the shelves and some drug products contained excessive dust and were not properly cleaned.

32. She also observed seven loose pills on the floor and an active roof leak in nine areas of the Pharmacy.

33. Missouri law requires that pharmacies be kept in sanitary condition, to-wit:

> (F) All pharmacies shall be maintained in a clean and sanitary condition at all times. Any procedures used in the dispensing, compounding and admixture of drugs or drug-related devices must be completed under clean and, when recommended, aseptic conditions. 20 CSR § 2220-2.010(1)(F).

34. Excessive dust buildup on the shelves and drug products, pills on the floor and nine active leaks in the Pharmacy roof was not clean or sanitary and was in violation of 20 CSR § 2220-2.010(1)(F).

c. Outdated Drug Products in Active Inventory

35. During her September 26, 2017, inspection of the Pharmacy, Inspector Wolzak reviewed the active inventory of the Pharmacy.

36. Inspector Wolzak found at least eight expired drug products – one return to stock, five return to stock compound preparations and two batch compound preparations – in active inventory.

37. Missouri law requires:

> (V) No outdated drugs are dispensed or maintained within the active inventory of the pharmacy, including prescription and related nonprescription items. 20 CSR § 2220-2.090(2)(V).

38. By failing to keep expired drug products out of the active inventory, the Pharmacy was in violation of 20 CSR § 2220-2.090(2)(V).

d. Removed/partially destroyed bottle label

39. During her September 26, 2017, inspection of the Pharmacy, Inspector Wolzak observed that the label on a manufacturer's stock bottle was partially torn off and the lot number and expiration date had been removed.

40. Missouri law states:

> (9) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if such act is done while such article is held for sale and results in such article being misbranded;
> § 196.015(9), RSMo

41. The Pharmacy violated § 196.015(9), RSMo, by selling medication from a manufacturer's stock bottle, the label of which had been partially destroyed and/or removed.

42. This was a repeat violation.

e. Prepackaging Violations

43. During her September 26, 2017, inspection, Inspector Wolzak reviewed the prepacked drug products in the Pharmacy's Yuyama machine.

44. Missouri law allows pharmacies to prepackage drug products under certain conditions, to wit:

> (1) A pharmacist or pharmacy may prepackage drugs for other than immediate dispensing purposes provided that the following conditions are met:
>
> > (C) The maximum expiration date allowed for prepacked drugs shall be the manufacturer's expiration date or twelve (12) months, whichever is less;
>
> (2) The term prepacked as used in this rule is defined as any drug which has been removed from the original manufacturer's container and is placed in a dispensing container for other than immediate dispensing to a patient.
> 20 CSR § 2220-2.130(1)(C).

45. Inspector Wolzak found drug products in the Yuyama machine which were assigned an expiration date of greater than one year in violation of 20 CSR § 2220-2.130(1)(C).

f. Failure to Offer Patient Counseling

46. During her September 26, 2017, inspection of the Pharmacy, Inspector Wolzak observed a failure to offer patient counseling to all patients who picked up prescriptions.

47. Missouri law requires:

> (1) Upon receipt of a prescription drug order and following a review of the available patient information, a pharmacist or his/her designee shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of each patient. Counseling shall be conducted by the pharmacist or a pharmacy extern under the pharmacist's immediate supervision to allow the patient to safely and appropriately utilize the medication so that maximum therapeutic outcomes can be obtained . . . 20 CSR § 2220-2.190(1)

48. By failing to offer each and every patient of the Pharmacy counseling, the Pharmacy was in violation of 20 CSR § 2220-2.190(1).

49. The Pharmacy was issued a compliance notice with regard to this violation to which it responded that employees were retrained on this aspect of the law and were told disciplinary action will result if they do not comply.

g. Controlled substance prescription labeling violations

50. During her September 26, 2017, inspection of the Pharmacy, Inspector Wolzak reviewed controlled substance prescriptions that were being filled by the Pharmacy.

51. She observed that controlled substance prescription nos. 2464289-05278, 2464301-05278, 2463959-05278, and 2463256-05278 written by a nurse practitioner did not contain the name of the collaborating physician on the prescription label.

52. Pursuant to § 195.100.5, RSMo:

> 5. Whenever a pharmacist or practitioner sells or dispenses any controlled substance on a prescription issued by a physician, physician assistant, dentist, podiatrist, veterinarian, or advanced practice registered nurse, the pharmacist or practitioner shall affix to the container in which such drug is sold or dispensed a label showing his or her own name and address of the pharmacy or practitioner for whom he or she is lawfully acting; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the physician, physician assistant, dentist, podiatrist, advanced practice registered nurse, or veterinarian by whom the prescription was written; the name of the collaborating physician if the prescription is written by an advanced practice registered nurse or the

> supervising physician if the prescription is written by a physician assistant, and such directions as may be stated on the prescription. No person shall alter, deface, or remove any label so affixed.

53. The Pharmacy's failure to include the name of the collaborating physician on controlled substance prescription labels written by nurse practitioners violated § 195.100.5, RSMo.

54. This was a repeat violation.

55. The Pharmacy was issued a compliance notice with regard to this violation to which it responded that employees were retrained on including mid-level practitioners' names in the signature area and pharmacists will be held accountable and prescriptions will be spot-checked by the pharmacy manager.

h. Immunization Protocol Violations

56. During her September 26, 2017, inspection of the Pharmacy, Inspector Wolzak found that the Pharmacy immunization protocols and vaccine administration records were incomplete.

57. The Pharmacy's immunization protocol was not signed and dated by pharmacist A.H. who administered a Zostavax vaccination on September 22, 2017.

58. The Pharmacy's vaccine administration records also failed to indicate the anatomic site and/or route of the administration.

59. Missouri law gives a licensed pharmacist the authority to give immunizations, to wit:

> 1. The "practice of pharmacy" means . . . the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis vaccines by written protocol authorized by a physician for persons

twelve years of age or older as authorized by a physician for a specific patient as authorized by rule; . . .
§338.010.1, RSMo.[1]

60. However, Missouri law requires very specific requirements to be met in order for pharmacists at the Pharmacy to be authorized to give immunizations, to-wit:

> (1) A pharmacist may administer vaccines authorized by Chapter 338, RSMo, pursuant to a written protocol authorized by a physician licensed pursuant to Chapter 334, RSMo, who is actively engaged in the practice of medicine.
>
> > (A) A pharmacist shall administer vaccines in accordance with treatment guidelines established by the Centers for Disease Control (CDC) and in accordance with manufacturer's guidelines, provided that a pharmacist shall not administer vaccines to persons under twelve (12) years of age.
> >
> > (B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirement.
>
> (2) A pharmacist may not delegate the administration of vaccines to another person, except to a pharmacist intern who has met the qualification under subsections 4(B), (C), and (D) and is working under the direct supervision of a pharmacist qualified to administer vaccines.
>
> (3) The authorizing physician is responsible for the oversight of, and accepts responsibility for, the vaccines administered by the pharmacist.
>
> (4) Pharmacist Qualifications. A pharmacist who is administering a vaccine authorized by Chapter 338, RSMo, must:
>
> > (A) Hold a current unrestricted license to practice pharmacy in this state;
> >
> > (B) Hold a current cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross or equivalent;
> >
> > (C) Successfully complete a certificate program in the administration of vaccines accredited by the Accreditation

[1] As in effect on September 22, 2017.

Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy;

(D) Maintain documentation of the above certifications;

(E) Complete a minimum of two (2) hours (0.2 CEU) of continuing education as defined per calendar year related to administration of vaccines. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal.

(F) Provide documentation of Subsections (A), (B), (C), and (E) of this section to the authorizing physician(s) prior to entering into a protocol or administering vaccines; and

(G) On a yearly basis prior to administering vaccines, establish a new protocol with the authorizing physician and notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), (E), and (F) of this section.

(5) Administration by Written Protocol with a Missouri Licensed Physician.

(A) A pharmacist may enter into a written protocol with a physician for the administration of vaccines authorized by Chapter 338, RSMo, provided that a pharmacist shall be prohibited from administering vaccines to patients under twelve (12) years of age. The physician must be no further than fifty (50) miles by road, using the most direct route available, from the pharmacist who is administering the vaccine. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must include the following:

1. The identity of the participating pharmacist and physician, including signatures;
2. Time period of the protocol;
3. The identification of the vaccines which may be administered;
4. The identity of the patient or groups of patients to receive the authorized vaccine(s);

5. The identity of the authorized routes and anatomic sites of administration allowed;
6. A provision to create a prescription for each administration under the authorizing physician's name;
7. A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. A provision establishing the length of time the pharmacist shall observe an individual for adverse events following an injection;
9. A provision establishing the disposal of used and contaminated supplies;
10. The street address of the pharmacy or other locations at which the pharmacist may administer the authorized vaccine;
11. Record-keeping requirements and procedures for notification of administration; and
12. A provision that allows for termination of the protocol at the request of any party to it and at any time.

(B) The protocol, and any subsequent amendments or alterations, shall be signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its content and agree to follow the terms of the protocol. The authorizing physician and pharmacist shall each maintain a copy of the protocol from the beginning of implementation to a minimum of eight (8) years after termination of the protocol.

(6) Record Keeping

(A) A pharmacist administering vaccines pursuant to this rule shall maintain a record of each administration which shall include:

1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;
3. The name, dose, manufacturer, lot number, and expiration date of the vaccine;
4. The name and address of the patient's primary health care provider, as identified by the patient;

5. The name or identifiable initials of the administering pharmacist; and
6. The nature of an adverse reaction and who was notified, if applicable.

(B) If the vaccine was administered on behalf of a pharmacy, the pharmacist shall ensure the records required by subsection 6(A) of this rule are promptly delivered to the pharmacy.

(C) Within seventy-two hours (72) hours after administration of a vaccine, the administering pharmacist shall obtain a prescription from the authorizing physician for the drug dispensed or shall create a prescription, as authorized by protocol documenting the dispensing of the drug. Notwithstanding any other provision of this rule, prescription records shall be maintained as provided by Chapter 338, RSMo, and the rules of the board.

(D) The records required by this rule shall be maintained securely and confidentially as follows:

1. If the vaccine is administered on behalf of a pharmacy, both the pharmacy and the administering pharmacist shall ensure that all records required by this rule are maintained at the pharmacy separate from the prescription files of the pharmacy. If the vaccine is not being administered on behalf of the pharmacy, all records shall be maintained securely and confidentially by the administering pharmacist at an address that shall be identified in the protocol prior to administering the vaccine; and
2. Records shall be maintained for two (2) years from the date of such record and shall be made available for inspecting and copying by the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives. Records maintained at a pharmacy must be produced during an inspection by the board and/or their authorized representatives. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the State Board of Pharmacy and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

(7) Notification Requirement

> (A) A pharmacist administering vaccines authorized by Chapter 338, RSMo, shall notify the authorizing physician within seventy-two (72) hours after administration of the following:
>
> 1. The identity of the patient;
> 2. The identity of the vaccine(s) administered;
> 3. The route of administration;
> 4. The anatomic site of the administration;
> 5. The dose administered; and
> 6. The date of administration.
>
> (B) The pharmacist shall provide a written report to the patient's primary care provider, if different than the authorizing physician, containing the documentation required in subsection (A) of this section within fourteen (14) days of the administration.
>
> (C) In the event of any adverse event or reaction experienced by the patient pursuant to a written protocol, the pharmacist shall notify the patient's primary care provider and authorizing physician, if different, within twenty-four (24) hours after learning of the adverse event or reaction.
>
> (D) A pharmacist administering vaccine(s) shall report the administration to all entities as required by state or federal law.
>
> (E) Documentation that notifications required by this rule have been sent must be maintained as provided in section (6) of this rule. 20 CSR § 2220-6.050.[2]

61. The Pharmacy's immunization protocol was deficient because it lacked the date and signature of all participating pharmacists in violation of 20 CSR § 2220-6.050(5)(B).

62. The Pharmacy was issued a compliance notice with regard to this violation to which it responded that the Pharmacy was waiting for the updated protocol to be available before pharmacist A.H. could immunize.

63. The Pharmacy's administration records also were deficient because they lacked the anatomic site and/or route of administration in violation of 20 CSR § 2220-6.050(6)(A)2.

[2] All citations to 20 CSR § 2220-6.050 refer to the regulation in effect at the time of the violations.

i. Medical Prescription Order Violations

64. During her September 26, 2017, inspection of the Pharmacy, Inspector Wolzak reviewed the Pharmacy's records of administrations by prescription order.

65. A prescription for yellow fever vaccine administered by a pharmacist on September 19, 2017 was missing the required statement that it was to be "administered by a pharmacist" and the route of administration.

66. At the time of the inspection, the Pharmacy's administration record for the yellow fever vaccine also was missing the route of administration and anatomic site.

67. In order for a pharmacist to administer by medical prescription order, Missouri law requires:

> (5) Requirements of Medical Prescription Order. The medical prescription order from a licensed prescriber must contain at a minimum the following:
>
> (A) The name of the licensed prescriber issuing the order;
> (B) The name of the patient to receive the drug;
> (C) The name of the drug and dose to be administered;
> (D) The route of administration;
> (E) The date of the original order;
> (F) The date or schedule, if any, of each subsequent administration; and
> (G) A statement that the drug is to be administered by a pharmacist.
>
> (6) Record Keeping.
>
> (A) A pharmacist who administers a drug pursuant to a medical prescription order shall maintain the following records regarding each administration. These records must be separate from the prescription files of a pharmacy.
>
> 1. The name, address, and date of birth of the patient;
> 2. The date, route, and anatomic site of the administration;
> 3. The name, dose, manufacturer, lot number, and expiration date of the drug;
> 4. The name and address of the patient's primary health care provider, as identified by the patient;
> 5. The name or identifiable initials of the administering pharmacist; and

> 6. The nature of an adverse reaction and who was notified, if applicable.
>
> (B) All records required by this regulation shall be kept by the pharmacist and be available for two (2) years from the date of such record for inspecting and copying by the State Board of Pharmacy and/or its authorized representatives. 20 CSR § 2220-6.040(5)-(6).[3]

68. The Pharmacy's administration of a vaccine pursuant to a medical prescription order that failed to contain language that administration by a pharmacist was authorized violated 20 CSR § 2220-6.040(5)(G).

69. This was a repeat violation.

70. The Pharmacy was issued a compliance notice with regard to this violation to which it responded that the nurse practitioner who wrote the prescription order was re-educated and the pharmacists were instructed on checking hard copies and calling to verify the missing information.

71. The Pharmacy's administration of a vaccine pursuant to a medical prescription order that failed to contain the route of administration violated 20 CSR § 2220-6.040(5)(D).

72. The Pharmacy's administration record was deficient because it lacked the anatomic site and/or route of administration in violation of 20 CSR § 2220-6.040(6)(A)2.

j. Compounding Violations

73. During her September 26, 2017, inspection of the Pharmacy, Inspector Wolzak reviewed compounded drug records and found several that did not comply with Missouri law.

74. For compounded drug products, Missouri law requires:

> (7) Appropriate quality control measures shall be maintained by the pharmacy and its staff over compounding methods.

[3] All citations to 20 CSR § 2220-6.040 refer to the regulation in effect at the time of the violations.

(A) Such methods shall include the following and shall be followed in the execution of the drug compounding process. A separate log shall be maintained which includes:

1. Methods for the compounding of drug products to insure that the finished products have the identity, strength, quality and purity they purport or are represented to possess;
2. Date of compounding;
3. Identity of the compounding pharmacist;
4. A listing of the drug products/ingredients and their amounts by weight or volume;
5. Description of the compounding process and the order of drug product/ingredient addition, if necessary for proper compounding;
6. The identity of the source, lot number and the beyond use date of each drug product/ingredient, as well as an in-house lot number and beyond use date for bulk compounded products; and
7. An identifying prescription number or a readily retrievable unique identifier for which the compound was dispensed.

* * *

(D) Any excess compounded products shall be stored and accounted for under conditions dictated by its composition and stability characteristics to insure its strength, quality and purity. Excess product shall be labeled with the name of the drug(s), an in-house lot number and beyond-use date. 20 CSR § 2220-2.400(7)(A), (D)

75. In several instances, the compound log maintained by the Pharmacy was incomplete and did not contain a description of the compounding method used.

76. The Pharmacy also failed to enter compound prescription no. 2451770-05278 for TAC (triamcinolone) 0.1%/Eucerin, and compound prescription no. 2440377-05278 TAC 0.01%/Eucerin in its compound log.

77. The Pharmacy's batch compound logs did not contain prescription numbers for the compound dispensed.

78. The Pharmacy's failure to maintain compound logs with all information required by law is in violation of 20 CSR § 2220-2.400(7)(A).

79. Inspector Wolzak also observed that compounded prescription nos. 2456263-05278 and 2382133-05278 returned to stock were labeled with incorrect lot numbers on the container labels.

80. Compounded prescription nos. 2328747-05278, 2451700-05278 and 2440377-05278 returned to stock were not labeled with in-house lot numbers on the product labels.

81. The Pharmacy's compound preparations that were returned to stock and failed to contain accurate lots numbers violated 20 CSR § 2220-2.400(7)(D).

82. This was a repeat violation.

83. Inspector Wolzak also observed that the Pharmacy had assigned batch compound 20170413-01 Quinacrine 100mg capsules, prescription no. 2382133, a beyond-use date of October 31, 2017, when the compound ingredient lactose anhydrous powder had an expiration date of July 2017.

84. Missouri law states:

> (4) Beyond-use date: A date after which a compounded preparation should not be used and is determined from the date the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their beyond-use dates must be assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products. 20 CSR § 2220-2.400(4).

85. Missouri law prohibits:

> (1) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;
>
> (2) the adulteration or misbranding of any food, drug, device, or cosmetic; § 196.015, RSMo

86. A drug or device shall be deemed to be adulterated in Missouri:

> (7) If it is a drug and any substance has been mixed or packed therewith so as to reduce its quality or strength, or substituted wholly or in part therefor. § 196.095(7), RSMo.

87. By assigning a beyond-use date to a compound which was greater than the compound ingredient's expiration date, the Pharmacy caused the compound to be adulterated and/or misbranded in violation of 20 CSR § 2220-2.400(4), § 196.015(1)-(2), RSMo, and § 196.095(7), RSMo.

Subsequent Internal Audits

88. Subsequent to Inspector Wolzak's inspections, Respondent conducted three audits which resulted in additional controlled substance loss reports to the DEA and BNDD on July 21, 2017, July 10, 2018, and July 19, 2018 and an amendment to the July 19, 2018 report.

89. In total, these additional audits reported additional losses of 9,635 dosage units and 7,346 mL.

90. The Pharmacy indicated on the July 21, 2017 DEA loss report that the security measures it would implement to deter future thefts or losses were "count inventory more frequently" and "installed new camera angle to monitor C2 cabinet."

91. The Pharmacy indicated on the July 10, 2018 DEA loss report that the security measures it would implement to deter future thefts or losses were "perpetual inventory" and "steel safes installed with only RPH codes."

92. The Pharmacy indicated on the July 19, 2018 DEA loss report that the security measures it would implement to deter future thefts or losses were "perpetual inventory has been utilized" and "C2 and high risk drugs in steel safe – plus time delay."

93. Respondent failed to provide adequate security or effective controls and procedures to guard against and deter loss and/or theft of its controlled substances as reflected on the July 21, 2017, July 10, 2018, and July 19, 2018 loss reports in violation of 20 CSR § 2220-2.010(1)(H).

September 17, 2018 Inspection

94. On or around September 17, 2018, Board Inspector Elaina Wolzak conducted a routine inspection of the Pharmacy.

95. She observed additional violations of Missouri regulations.

a. Unsanitary conditions

96. During her September 17, 2018, inspection of the Pharmacy, Inspector Wolzak observed an active roof leak in the Pharmacy.

97. She also observed that the Pharmacy's ceiling vents were covered with a black substance and drugs were being stored on the floor.

98. She also found hair on the Pharmacy's shelves.

99. Hair on the shelves, drugs stored on the floor, an active leak in the Pharmacy roof and a black substance on the ceiling vents was not clean or sanitary in violation of 20 CSR § 2220-2.010(1)(F).

100. This was a repeat violation.

101. The Pharmacy was issued a second compliance notice with regard to this violation.

b. Medical Prescription Order Violations

102. During her September 17, 2018, inspection of the Pharmacy, Inspector Wolzak reviewed the Pharmacy's records of administrations by medical order.

103. At the time of the inspection, the Pharmacy's administration record for prescription no. 2548438 for an MMR vaccination written on February 16, 2018 was missing the route of administration.

104. The Pharmacy's record of administration of a vaccine pursuant to a medical prescription order that failed to contain the route of administration violated 20 CSR § 2220-6.040(5)(D).

105. The Pharmacy's administration record was deficient because it lacked the route of administration in violation of 20 CSR § 2220-6.040(6)(A)2.

106. This was a repeat violation.

107. The Pharmacy was issued a compliance notice with regard to this violation.

c. Violation of labeling requirements

108. During her September 17, 2018, inspection of the Pharmacy, Inspector Wolzak reviewed the Pharmacy's return to stock prescriptions.

109. She observed that multiple prescription numbers on labels of return to stock prescriptions had been marked out or were not visible.

110. Missouri law requires the following information on labels of return to stock prescriptions:

> (3) Pharmacists and pharmacies may return to stock prescriptions that have not been received by the patient and shall delete the dispensing from the pharmacy's records and reverse the claim with the third party payor, if applicable. In order for a product to be returned to stock, it must have been stored at all times at the manufacturer's labeled storage requirements. The drug must be maintained in the patient container with the dispensing date, prescription number, and name of drug visible. The expiration date of the drug shall become the lesser of one (1) year from the dispensing date on the label or the manufacturer's original expiration date, if known.
> 20 CSR § 2220-3.040(3).

111. The Pharmacy's failure to maintain the prescription numbers on the return to stock prescriptions violated 20 CSR § 2220-3.040(3).

d. Prepackaged drug violations

112. During her September 17, 2018, inspection of the Pharmacy, Inspector Wolzak reviewed the Pharmacy's prepackaged drugs.

113. She found a container with tablets marked with "UL250" in active inventory with no label whatsoever.

114. She found another container of prepackaged Phentermine 15mg capsules and a container of prepackaged Hydrocortisone 10mg tablets, the labels of which did not have expiration dates or lots numbers.

115. Missouri law requires the following for prepackaged drugs:

> (1) A pharmacist or pharmacy may prepackage drugs for other than immediate dispensing purposes provided that the following conditions are met:
>
> > (D) Any prepacked drug must have a label affixed to it which contains, at a minimum, the name and strength of the drug, the name of the manufacturer or distributor, an expiration date as defined in subsection (1)(C) and lot number. Pharmacies that store drugs within an automated counting device may, in place of the required label, maintain records for lot numbers and expiration dates that are required on the label as long as it is fully traceable and is readily retrievable during an inspection.
>
> (2) The term prepacked as used in this rule is defined as any drug which has been removed from the original manufacturer's container and is placed in a dispensing container for other than immediate dispensing to a patient. 20 CSR § 2220-2.130(1)(D).

116. The Pharmacy violated 20 CSR 2220-2.130(1)(D) by storing prepackaged drugs in containers without labels or with labels that did not contain expiration dates or lots number.

e. Dispensing error

117. During her September 17, 2018, inspection of the Pharmacy, Inspector Wolzak reviewed the Pharmacy's dispensing records.

118. She observed that prescription no. 2645274 was written for cephalexin 500mg #21 with instructions to "take one capsule three times daily," but was dispensed by the Pharmacy with the instructions to "take one capsule four times daily."

119. A quality assurance report was issued to the Pharmacy on the date of the inspection for this dispensing error.

120. The pharmacist who dispensed prescription no. 2645274 failed to properly exercise professional discretion when the prescription was dispensed with incorrect instructions.

f. Immunization record violations

121. During her September 17, 2018, inspection of the Pharmacy, Inspector Wolzak reviewed the Pharmacy immunization protocol and immunization administration records.

122. Administration records for patients M.P., S.P., K.K., M.L. and G.W. for FluZone High-Dose erroneously showed the protocol physician as the patients' primary care physician.

123. The Pharmacy's administration records were deficient because they failed to state the name and address of the primary health care provider for patients M.P., S.P., K.K., M.L. and G.W. in violation of 20 CSR § 2220-6.050(6)(A)4.

JOINT CONCLUSIONS OF LAW

124. Respondent is subject to discipline under 20 CSR § 2220-2.010(1)(O) which states:

> (O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

125. Respondent is liable for violations of Chapter 338 or other relevant laws because, "any permit holder . . . at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation." § 338.210.5, RSMo.

126. Respondent's actions violate the terms of the 2016 Agreement in that it has failed to comply with all provisions of Chapter 338, Chapter 195, Chapter 196, RSMo., and all applicable drug laws, rules and regulations.

127. Respondent's conduct is cause for disciplinary action against its permit to operate a pharmacy under §338.055 RSMo, which provides:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one of any combination of the following causes.
>
> * * *
>
> (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;
>
> * * *
>
> (12) Failure to display a valid certificate or license if so required by this chapter or any rule promulgated hereunder;
>
> * * *
>
> (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government . . .

128. Since Respondent violated the disciplinary terms contained in the 2016 Agreement, the Board is authorized under the 2016 Agreement to impose further discipline on Respondent's permit in accordance with Section 338.055.3, RSMo, which provides, in pertinent part:

> . . . the board may impose additional discipline on a licensee, registrant or permittee found to have violated any disciplinary terms previously imposed under this section or by agreement. §338.055.3, RSMo.

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Sections 324.042, 338.055.3, 536.060, and 621.045.1, RSMo:

A. Respondent's pharmacy permit, numbered 2000157695 shall be placed on **PROBATION for a period of THIRTY (30) MONTHS.** The period of probation shall constitute the disciplinary period.

The following terms apply for the entire disciplinary period:

1. Respondent shall pay all required fees for licensing to the Board and shall renew its pharmacy license prior to October 31 of each licensing year.

2. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

3. If requested, Respondent shall provide the Board a list of all licensed pharmacists employed by the Respondent, and the individuals' current home addresses and telephone numbers.

4. If, after disciplinary sanctions have been imposed, Respondent fails to keep its pharmacy license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

5. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its disciplinary order.

6. Respondent shall not serve as an intern training facility for interns.

7. The Permit Holder must establish a two-hour pharmacist-in-charge ("PIC") concentrated compliance training program to be completed by any PIC employed at this Pharmacy store (#05278). The PIC compliance training program must be

approved by the Board and must include training on Missouri's pharmacy compliance requirements, including, but not limited to, recordkeeping and record retrieval policies and procedures, Missouri's immunization requirements and 20 CSR 2220-2.090. The PIC employed at this Pharmacy shall complete the Board-approved training program(s) within ninety (90) days of the effective date of this Agreement, or within 90 days of the date on which the Board approves the training program, whichever is later. Training may be provided over multiple days and/or on a group basis. Walgreens shall notify the Board office in writing within sixty (60) days of this Agreement, or within sixty (60) days of the Board's approval of the training program, whichever is later, of the training date(s), time(s) and location(s). A Board inspector shall be allowed to attend and present information during the required training program(s) upon request. Walgreens shall maintain documentation of the PIC training date(s) in the pharmacy's records; the required documentation must be produced on inspection or at the request of the Board. If the PIC changes and the new PIC has not completed the training program, the new PIC shall be required to complete the Board approved training program within ninety (90) days after being designated PIC, or within 90 days of the Board's approval of the training program, if not approved at the time he or she became the new PIC, whichever is later. Walgreens #05278 shall maintain documentation of its PIC's training date(s), with its applicable pharmacy records. The required documentation must be produced on inspection, or at the request of the Board.

8. Within thirty (30) days of the effective date of this Agreement, Walgreens shall designate and provide the PIC specific time periods each week to review pharmacy operations and compliance. These periods shall not be shorter than two (2) hours. The designated days and allowed time frame must be documented, and available for review by a Board inspector. During this dedicated time, the PIC will not be required to be involved in dispensing or administration activities.

9. Respondent shall select a pharmacist consultant for the purpose of reviewing and insuring the pharmacy's compliance with all applicable laws and regulations. The consultant shall be a Missouri licensed pharmacist whose license is current and not subject to disciplinary action by the Board. The consultant may be an employee of Walgreens. The consultant shall not be employed by, assigned to, or have worked for Walgreens #05278, in the past six (6) months. The consultant shall not be a member of Walgreens management or the PIC for Walgreens #05278. Within thirty (30) days of the beginning of probation, Respondent shall submit documentation and credentials of its chosen consultant to the Board office for approval. Within thirty (30) days of the beginning of probation the said consultant shall visit the pharmacy, evaluate and provide corrective actions to remedy the issues outlined in this agreement, conduct a review for compliance with all applicable laws and regulations using the Board's Pharmacy Self-Assessment Form, and submit a written report to the Board office within thirty (30) days of the visit. The consultant's report shall include the suggested corrective actions, a timeline for the pharmacy to complete such corrective actions, items/areas reviewed for compliance with applicable laws and regulations during the visit, any deficiencies

noted, and a plan to correct any deficiencies noted. The consultant shall then conduct similar visits and provide ongoing reports to the Board office on a three (3) month cycle for the first two years of the probationary period and on a six (6) month cycle thereafter for the remainder of the probationary period. All consultant reports are due at the Board office within thirty (30) days of the consultant's visit to the pharmacy. The consultant shall be hired at Respondent's expense.

10. In addition to the required PIC training program, the current PIC for Walgreens #05278 and any subsequent PIC for the pharmacy must review the Board Inspection reports for the previous seven (7) years. The PIC for Walgreens #05278 must also complete the Board's Pharmacy Self-Assessment Guide along with, and in the physical presence of, the pharmacy's District Manager or the Board approved Internal Consultant. The Pharmacy's Self-Assessment Guide must be completed before January 15th and July 15th of each year during the probationary period. The Completed Self-Assessment Guide must be documented in writing and maintained in the pharmacy's records. All records must be produced on inspection or at the request of the Board.

11. To ensure compliance, the following self-inspections shall be required each year during the probationary period for Walgreens # 05278:

a. Respondent's District Manager shall conduct monthly self-inspections of the pharmacy on or before the 15th of each month. After the first six (6) months of probation, the Respondent's District Manager shall conduct bi-monthly self-inspections of the pharmacy, alternating each month with the Respondent's Healthcare Supervisor.

b. Respondent's Healthcare Supervisor shall perform a monthly self-inspection of the pharmacy on or before the last day of each month, provided the self-inspection must be completed after the District Manager's required monthly inspection. After the first six (6) months of probation, the Respondent's Healthcare Supervisor shall conduct bi-monthly self-inspections of the pharmacy, alternating each month with the Respondent's District Manager.

c. Respondent's store manager shall conduct quarterly self-inspections of the pharmacy on or before January 15th, April 15th, July 15th, and October 15th of each year during the probationary period.

d. Respondent's PIC shall conduct bi-annual self-inspections on or before January 15 and July 15 of each year.

e. All self-inspections required by this Order/Settlement Agreement shall be completed using the Board's Pharmacy Self-Assessment Guide. The Completed Self-Assessment Guide must be documented in writing and maintained in the pharmacy's records. All records must be produced on inspection or at the request of the Board.

12. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.

13. All required prescription records and records relating to immunizations or medication administered by medical prescription order shall be produced on inspection or at the request of the Board.

14. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.

15. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

B. Upon the expiration of said discipline, Respondent's permit as a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent.

C. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

D. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of

this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

E. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

F. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs, and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. §1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

The Settlement Agreement goes into effect on the date it is signed by the Board's Executive Director.

RESPONDENT

WALGREENS PHARMACY #05278

By: _____
As authorized representative for
Walgreens Pharmacy #05278

Printed: Rina Shah, GVP - Specialty & Retail Pharmacy

Date: 08/26/2019

PETITIONER

MISSOURI BOARD OF PHARMACY

By: _____
Kimberly Grinston
Executive Director

Date: 9/19/19

NEWMAN, COMLEY & RUTH P.C.

By: _____
Alicia Embley Turner #48675
601 Monroe, Suite 301
P.O. Box 537
Jefferson City, MO 65102-0537
Tel: (573) 634-2266
Fax: (573) 636-3306
turnera@ncrpc.com

Attorneys for Petitioner